

NOV - 8 2005

510(K) SUMMARY

Submitted by:

Organogenesis Inc.
150 Dan Road
Canton, Massachusetts 02021

Contact

Patrick R. Bilbo
Telephone: (781) 401-1155
Facsimile: (781) 575-1570

Date: October 21, 2005

Device:

Trade Name:	FortaDerm™ Antimicrobial PHMB Wound Dressing coated with 0.1% Polyhexamethylene Biguanide Hydrochloride (PHMB)
Common/Usual Name:	Topical Wound Dressing, Wound Management Biomaterial
Classification Name:	Dressing, Wound (KMF)
Classification:	Unclassified

Predicate Devices:

The relevant predicate devices are FortaDerm™ (PuraPly™) Wound Dressing (K011026) manufactured by Organogenesis, Inc. and Xcell Antimicrobial Cellulose Wound Dressing (K024054) manufactured by Xylos® Corporation.

Statement of Substantial Equivalence:

The FortaDerm™ Antimicrobial PHMB Wound Dressing is similar with respect to intended use, technological characteristics, materials and physical construction to the predicate devices in terms of section 510(k) equivalency.

Intended Use:

The FortaDerm™ Antimicrobial PHMB Wound Dressing is intended for the management of wounds and as an effective barrier to resist microbial colonization within the dressing and reduce microbes penetrating through the dressing. FortaDerm™ Antimicrobial PHMB Wound Dressing may be used for the management of: partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, wound

dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds.

The device is intended for one-time use.

Device Description:

FortaDerm™ Antimicrobial PHMB Wound Dressing consists of two layers, crosslinked sheet of fenestrated sheet of porcine intestinal collagen coated with 0.1 % Polyhexamethylene Biguanide hydrochloride (PHMB). FortaDerm Wound Dressing is supplied dry in sheet form in sizes ranging from 4 x 4 cm to 12 x 36 cm. The device is packaged in sterile, sealed single pouches.

Performance Data:

FortaDerm™ Antimicrobial PHMB Wound Dressing was subjected to a number of tests to assess biocompatibility and performance. The device passed the requirements of all tests.

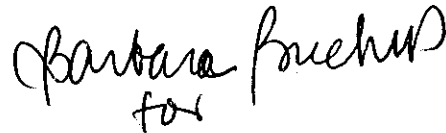


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,

A handwritten signature in black ink that reads "Barbara Buckner" with a small "for" written below it.

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051647

Device Name: FortaDerm™ Antimicrobial PHMB Wound Dressing

Indications for Use:

The FortaDerm™ Antimicrobial PHMB Wound Dressing is intended for the management of wounds and as an effective barrier to resist microbial colonization within the dressing and reduce microbes penetrating through the dressing. FortaDerm™ Antimicrobial PHMB Wound Dressing may be used for the management of: partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds.

The device is intended for one-time use.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

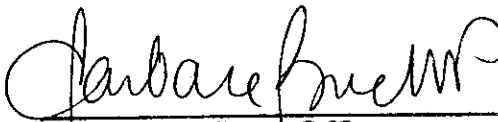
AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)



Page ___ of ___

(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K051647